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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427 | | | | |
| | | | EXAMINER HAND, MELANIE JO | |
| | | | ART UNIT 3761 | PAPER NUMBER |

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,078

Applicant(s)

DAVIS ET AL.

Examiner

Melanie J. Hand

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>various(5)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for priority as a continuation-in-part of copending Application No. 10/263,518, filed on October 3, 2002.

Information Disclosure Statements

The information disclosure statements (IDS) submitted on July 16, 2004, February 18, 2005, September 23, 2005, November 17, 2005 and May 22, 2006 were each filed after the mailing date of the Application on April 8, 2004. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58 and 61-66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-31 of copending Application No. 10/263,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a skin antiseptic composition dispenser comprising a container defining an interior volume, a skin antiseptic composition located within the interior volume, dispensing means for dispensing the composition wherein said container is impermeable to liquid and vapor phases of said composition and said container has at least one layer that is substantially impermeable to gaseous ethylene oxide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 59,60 and 62 are objected to because of the following informalities: the phrase "the barrier layer" lacks sufficient antecedent basis in claim 58 from which claims 59, 60 and 62 depend. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the

international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 58-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Dischler (U.S. Patent No. 6,585,693).

With respect to **Claims 58,64-67,69,70,73,74**: Dischler teaches a single-dose syringe 24 comprising cylindrical syringe body 62 (container) defining an interior volume, wherein said container is comprised of at least one polymeric layer (wall) that does not contain metal lamina. The interior volume defined by syringe body 62 contains second blister chamber 42 that houses injection prep fluid such as alcohol (skin antiseptic composition). Second blister chamber 42 is closed by cap 64 comprising fill port 52 (vent having vent orifice-claim 65), seal 50 (vent seal) and break zone 46 (collectively, the dispensing means). Cap 64 is joined to body 62 by thin web 44 (vent seal layer-claim 67) can be broken, allowing said antiseptic composition in second chamber 42 to escape and be delivered to a skin surface (claim 66). The polymeric layers of body 62 serve as barriers and are comprised of materials consistent with the stability, storage time and compatibility of the contents, and are therefore impervious to both liquid and vapor forms of said antiseptic. Dischler teaches polymers for the lamina, all of which are substantially water-impermeable (liquid and vapor) and thus will also be impermeable to gaseous ethylene oxide, as an ethylene oxide molecule is larger than a water molecule.

With respect to **Claim 59**: Dischler teaches a syringe body 62 having walls comprised of polymeric lamina and therefore teaches that the barrier covers 100% (i.e. at least 60%) (claim 60) of the walls of body 62. Applicant has not established sufficient criticality for having a barrier material that covers less than 100%, therefore this limitation is considered an optimization of the

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surface area of said barrier layer(s). It would be obvious to one of ordinary skill in the art to modify the barrier coverage area to be less than 100% as the blister chambers collectively are not coextensive with said walls and therefore would only need the barrier functionality in the areas adjacent said chambers. Leaving the remainder free of barrier material would facilitate transparency and visual inspection of said syringe.

With respect to **Claim 61**: Dischler does not explicitly teach any of the items set forth in claim 61, but does teach that second chamber 42 contains an injection prep or other sterilizing fluid, of which povidone (iodine complex) and chlorhexidine gluconate are examples that are well-known in the art, therefore it would be obvious to one of ordinary skill in the art to fill second chamber 42 with povidone.

With respect to **Claim 62**: Dischler teaches polyester as a polymer acceptable for construction of the polymer lamina of body 62.

With respect to **Claims 63,72,75**: Dischler teaches polyvinylidene chloride (halogenated polyolefin).

With respect to **Claim 68**: Dischler teaches that the barrier lamina are flexible.

With respect to **Claim 71**: Dischler teaches that the polymer lamina are attached to one another via additional heat sealable polymer (heat activated adhesive) lamina therebetween that function also as barrier lamina.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

